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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHN C. STROEBEL

Appeal 2014-009413
Application 13/412,120
Technology Center 3700

Before: JENNIFER D. BAHR, BRANDON J. WARNER, and LEE L. STEPINA, *Administrative Patent Judges*.

STEPINA, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellant appeals under 35 U.S.C. § 134 from a rejection of claims 1–3 and 5–12. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM and designate our affirmance as a NEW GROUND OF REJECTION under 37 C.F.R. § 41.50(b).

CLAIMED SUBJECT MATTER

The claims are directed to a method of providing a ventricular pacing pulse. Spec. 48 (Abstract). Claims 1, 6, and 10 are independent. Appeal Br. 14–15 (Claims App.). Claim 1, reproduced below, is illustrative of the claimed subject matter:

> 1. A method of selectively providing cardiac pacing with an implantable medical device comprising:
>
> setting a flag during a given cardiac cycle in response to ventricular activity; and
>
> precluding a ventricular pacing pulse during a current cardiac cycle if the flag is present at the onset of the current cardiac cycle; and
>
> wherein the given cardiac cycle is defined by an A-A interval.

Appeal Br. 14 (Claims App.).

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on appeal is:

Rueter	US 4,523,593	June 18, 1985
Limousin	US 5,318,594	June 7, 1994

REJECTION

Claims 1, 3, and 5–12 are rejected under 35 U.S.C. § 102(b) as anticipated by Limousin, or, in the alternative, under 35 U.S.C. § 103(a) as unpatentable over Limousin and Rueter.

OPINION

Claim 1

The Examiner finds that Limousin teaches "setting a flag during a given cardiac cycle in response to ventricular activity and precluding a ventricular pacing pulse during a current cardiac cycle if the flag is present at the onset of the current cardiac cycle." Final Act. 3 (citing Limousin, 2:10–38). Regarding the step of "precluding a ventricular pacing pulse" as recited in claim 1, the Examiner finds that, in Limousin, "if ventricular activity was detected, a flag somewhere in the system is *implied* to have been set in order *for the system to be switched into an AAI mode — with no pacing pulse delivered — if any R-waves are detected* during an AV interval." Final Act. 3–4 (emphases added). Thus, the Examiner finds that the AAI mode precludes a ventricular pacing pulse.

As an alternative to finding that Limousin implicitly discloses setting a flag, the Examiner finds that Rueter "teaches determining whether or not a flag has been set in order to deliver or withhold pacing" and "shows that when an R-wave is sensed, then a flag is set; when the flag is set, no pacing pulse is delivered." Final Act. 4. The Examiner also finds that in Rueter, "[i]f no flag has been set, then a ventricular pacing pulse is delivered. Final Act. 4 (citing Rueter, Fig. 4). The Examiner reasons that it would have been obvious to set a flag in Limousin after ventricular activity "to mark the event and notify the system to withhold a ventricular pacing pulse if the flag is present at the onset of the current cardiac cycle." Final Act. 4.

Appellant asserts "for purposes of interpreting the Examiner's rejection, we must understand that the AAI mode she refers to in Limousin is part of the DDD mode as presently defined." Appeal Br. 7.

We disagree. As set forth in the Final Action, the Examiner relies on Limousin's *switch into* the AAI mode "with no pacing pulse delivered" as qualifying as "precluding a ventricular pacing pulse" as recited in claim 1. Final Act. 3–4. Limousin discloses operating in the AAI mode and "automatically switching to pacing the heart in the DDD mode in response to a lack of atrio-ventricular condition, and automatically switching back to the AAI mode after atrio-conduction is restored." Limousin, 2:20–24. One of the stated objects in Limousin is "to provide a cardiac pacemaker of the DDD type that will operate in the DDD mode solely during period of crisis, and will operate in the AAI mode outside of the period of crisis." Limousin, 1:67–2:2. Specifically, in Limousin, "[t]he pacemaker will operate in the AAI mode as long as the atrio-ventricular conduction is normal, that is, as long as each atrial event E (outside of the refractory periods) is followed by a synchronous ventricular detection R." Limousin, 4:45–49. Thus, contrary to Appellant's contention, Limousin switches between distinct modes, namely, the DDD mode and the AAI mode, and the Examiner relies on a switch between these modes in the rejection of claim 1.

Appellant further asserts "[i]n the Limousin device, if the flag can be set during a 'given' cardiac cycle (A-A interval) the device is necessarily operating in what would now be called DDD mode. The flag, however, cannot be present at the onset of 'given' cardiac cycle (A-A interval) because it is necessarily set after the given cardiac cycle begins." Appeal Br. 8. Appellant asserts that "in Reuter, ventricular pacing is similarly [to the process in Limousin] not precluded in one cardiac cycle in response to a ventricular event in a previous cardiac cycle." Appeal Br. 8. Therefore, according to Appellant, "[b]oth references thus lack the same required

teaching. Adding flags to Limousin doesn't make the invention." Appeal Br. 8.

We disagree with Appellant's contention that a flag, in the Examiner's proposed combination of Limousin and Rueter, cannot be present at the onset of a cycle. Limousin teaches that its device, after switching to the AAI mode from the DDD mode, remains in the AAI mode until there is a crisis. *See, e.g.*, Limousin, 4:45–49. Thus, the AAI mode in Limousin, which precludes the ventricular pulse, persists from cycle to cycle until a need arises for the device to operate in the DDD mode. The Examiner's proposed modification to Limousin, based on the teachings of Rueter, adds a step of setting a flag for the purpose of marking the ventricular activity and notifying the system to withhold ventricular pacing pulses. *See* Final Act. 4. As Limousin's use of the AAI mode persists from cycle to cycle, it follows that the flag set by the Examiner's proposed modification to Limousin would also persist from cycle to cycle. Thus, the flag would be present at the beginning of a cycle occurring after the cycle in which the flag is set and would continue to be present in (and at the onset of) subsequent cycles until a crisis occurs.

Appellant asserts:

> When both an A-A cardiac cycle and ventricular sensing are available as required by the claims, the device of Limousin indisputably works exactly according to what would now be described as "DDD" mode. In DDD mode, following an atrial event, an A-V interval is initiated. In the absence of a sensed ventricular event during the A-V interval, *a ventricular pacing pulse is delivered on expiration of the A-V interval.*
>
> Yes, Limousin has an A-A cardiac cycle in a mode in which it is possible to set a flag in response to ventricular sensing in a given cardiac cycle. No, *it doesn't preclude ventricular pacing during any subsequent (current) cardiac.*

Appeal Br. 9 (italicization added).

Claim 1 requires "setting a flag during a given cardiac cycle in response to ventricular activity; and precluding a ventricular pacing pulse during a current cardiac cycle if the flag is present at the onset of the current cardiac cycle." *Id.* at 14 (Claims App.). Appellant does not explain persuasively why switching to the AAI mode from the DDD mode, and then maintaining the AAI mode for subsequent cycles as taught by Limousin, fails to qualify as the recited step of precluding ventricular pacing during a subsequent (current) cardiac cycle. This, along with the flag setting step provided by the Examiner's proposed modification to Limousin, satisfies the "setting" and "precluding" steps in claim 1.

Appellant also states:

> For the sake of completeness, it should also be mentioned that *when Limousin as disclosed operates according to what would now be defined as AAI mode, there would be no A-V interval initiated and no flag could be set in response to ventricular sensing*. How could there be? In AAI mode as now defined, and as in stand-alone mode in Limousin, there is never any ventricular pacing. There would be no need to set a flag to preclude it. Preclusion of ventricular pacing would occur in response to programming the AAI mode, not in response to any flag set during a previous cardiac cycle.

Appeal Br. 10 (italicization added).

Appellant's argument on this point is unpersuasive. The Examiner's proposed combination of Limousin and Rueter does not rely exclusively on the AAI mode of Limousin as corresponding to the recited step of *setting a flag* during a given cardiac cycle in response to ventricular activity. Rather, the rejection of claim 1 as unpatentable over Limousin and Rueter relies on the AAI mode of Limousin for precluding a ventricular pacing pulse and

adds to Limousin the teaching of flag setting explicitly taught by Rueter. *See* Final Act. 3–4.

Additionally, Appellant has not apprised us of error in the Examiner's reasoning for the proposed modification to Limousin to include flag setting as taught by Rueter. As the Examiner correctly finds (Final Act. 4), Rueter teaches the use of a flag to deliver or withhold pacing pulses (*see* Rueter, Abstract). The Examiner's finding that Limousin discloses a switch (from the DDD mode) to the AAI mode in which no ventricular pulses are provided, based on ventricular activity, is supported by a preponderance of the evidence. *See* Final Act. 3–4; *see also* Limousin, 2:10–38, 9:5–10. Limousin teaches that its AAI mode persists from cycle to cycle until a crisis arises. *See, e.g.*, Limousin, 1:67–2:2; 4:45–49. As the Examiner correctly finds, Rueter teaches a method of providing pacing pulses comparable to the one Limousin teaches. *See* Final Act. 4.[1] As the Examiner also correctly finds, when Rueter sets the flag, Rueter does not provide ventricular pacing. Rueter (Abstract). Appellant does not explain persuasively why the Examiner's rationale for including the setting of a flag as taught by Rueter in the method taught by Limousin, in order to mark the event, is inadequate. We agree with the Examiner that Limousin recognizes certain activity that triggers a switch to the AAI mode. *See* Final Act. 3–4 (stating "a flag somewhere in the system [of Limousin] is implied to have been set in order for the system to be switched into an AAI mode — with no pacing pulse delivered — if any R-waves are detected during an AV interval.").

[1] We understand the Examiner's statement "[w]here Limousin shows the same method as Limousin without referring to the response to ventricular activity as 'setting a flag'" on page 4 of the Final Action to inadvertently compare Limousin to itself rather than to Rueter.

Moreover, to make this recognition in Limousin explicit by setting a flag as taught by Rueter would merely have been the use of a known technique to improve a similar method to yield predictable results.

In the Reply Brief, Appellant states:

> [T]he Examiner has apparently not reviewed her previous arguments because they were directed to the switch from "AAI" mode in Limousin to the "DDD" mode in Limousin. The Examiner's Answer now expressly argues that the claims are met by the reverse, i.e. the switch "from DDD mode to AAI mode" in Limousin. This *new argument* makes less sense than the original argument. A ventricular sense event in the "DDD" mode of Limousin does not trigger a switch to "AAI" mode. The device remains in "DDD" mode and begins a new V-A escape interval.

Reply Br. 3 (emphasis added).

We disagree with Appellant's contention that the Examiner's position, in the Answer, relying on the switch to the AAI mode in Limousin, is new. Rather, the Final Office Action articulates this position, stating, "if ventricular activity was detected, a flag somewhere in the system is implied to have been set in order for the system to be switched *into an AAI mode* — with no pacing pulse delivered — if any R-waves are detected during an AV interval)." Final Act. 3–4.

Appellant further contends:

> The newly argued switch to "AAI" mode is in response to an atrial event, *not a ventricular event*, so there is no necessity that any flag set by a preceding ventricular event would persist after initiation if the V-A interval. Implicitly, it would be expected to have been cleared after initiation of the V-A interval timer, as it has no further disclosed function to perform. There is no implicit necessity or reasonable expectation that it would persist until a subsequent mode switch to "AAI" mode in response to a later atrial event.

> The Examiner's new argument with regard to claim 1 is clearly erroneous for this reason.

Reply Br. 4–5 (emphasis added); *see also* Reply Br. 6 (stating, "A V-sense event in DDD mode doesn't even trigger a mode change to "AAI" mode, so the whole argument seems nonsensical").

Appellant's argument on this point is both untimely and unpersuasive. As discussed above, the Examiner's position regarding the disclosure in Limousin with respect to switching *to an AAI mode* has not changed. Further, a preponderance of the evidence supports the Examiner's finding that the switch occurs in response to ventricular activity. For example, Limousin discloses:

> The process of the reversal of the pacemaker *to the AAI mode* takes place as soon as one of the following conditions is met:
>
> *(1) recovery of a spontaneous ventricular activity (a ventricular detection R occurs before the end of the AVD),*
>
> (2) transition from a paced atrial activity A to an atrial detection P (which may be indicating the end of a vagal syndrome),
>
> *(3) after 100 cycles with ventricular pacing (because the automatic DDD mode is intended for use with paroxystic conduction troubles).*

Limousin, 9:5–16 (emphases added); *see also* 3:34–50. Thus, Limousin teaches switching to the AAI mode in response to ventricular activity. As for Appellant's argument, raised for the first time in the Reply Brief, that any flag "would be expected to have been cleared after initiation of the V-A interval timer," because it has no disclosed function to perform, we are not persuaded inasmuch as Appellant points to no objective evidence that the flag would not perform a function. Further, Appellant provides no persuasive evidence or technical reasoning as to why the flag would be

cleared *before* a change in conditions in Limousin would prompt a return to the DDD mode from the AAI mode.

Appellant also asserts that "if the switch is from "DDD" to "AAI" as newly argued, then the "given" cardiac cycle is a V-V cycle. (V-A + A-V = V-V)." Reply Br. 5.

We do not agree with this argument. As explained above, Limousin maintains the AAI mode of operation until a crisis occurs causing a switch to the DDD mode. This period of time may include many consecutive cycles. Therefore, contrary to Appellant's assertion, the AAI mode in Limousin persists over at least an A-A cycle. Appellant's subsequent assertion that "[t]his is the reason that the Examiner's previous arguments all implicitly were directed to the 'given' and the 'current' cardiac cycles of the claims being the same cardiac cycle" (Reply Br. 5) is unpersuasive for the same reason.

As for Appellant's argument that "[f]or the sake of completeness, it is again noted that the 'given' cardiac cycle in 'DDD' mode[] isn't an A-A cardiac cycle anyway, because it begins with a ventricular event (V-A interval)," (*Id.* at 7) we are not apprised of Examiner error. Claim 1 recites "setting a flag during a given cardiac cycle in response to ventricular activity" and "wherein the given cardiac cycle is an A-A interval." Appeal Br. 14 (Claims App.). Appellant does not persuasively explain why the DDD mode in Limousin, operating over multiple consecutive cycles (*see e.g.*, Limousin, 9:5–16), would not encompass an A-A cycle (or multiple A-A cycles), regardless of the particular interval within an A-A cycle in which the DDD mode begins.

We have considered all of Appellant's arguments for the patentability of claim 1, but we are not apprised of Examiner error. Accordingly, we

affirm the Examiner's rejection of claim 1 as unpatentable over Limousin and Rueter. Because we affirm one of the alternative bases for the rejection, we affirm the rejection. Claims 3 and 5 depend from claim 1 (Appeal Br. 14 (Claims App.)), and Appellant makes no additional arguments for the patentability of these claims (*see* Appeal Br. 12–13). Accordingly, we affirm the rejection of claims 3 and 5 as unpatentable over Limousin and Rueter. Furthermore, our claim interpretation of claim 1 is different from the Examiner's, as explained below, and we therefore designate our affirmance of the rejection of claims 1 and 3–5 as a NEW GROUND of rejection.

Conditional Limitations

Claim 1

Although the Examiner made findings in Limousin and Rueter to address the "precluding" step in claim 1, it was not necessary for the Examiner to do so. During examination, claims are given their broadest reasonable interpretation consistent with the specification. *See In re Am. Acad. of Sci. Tech Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Claim 1 recites, in part "precluding a ventricular pacing pulse during a current cardiac cycle *if the flag is present at the onset* of the current cardiac cycle." Appeal Br. 14 (Claims App.). Appellant points to "steps, 502, 530, 535, 540, 545, 590 and 600 of Figure 15 as described at page 38, line 29 to page 40, line 11" as providing support for this limitation. Appeal Br. 3. Although we appreciate the flow-chart provided in Figure 15 includes certain decision steps and action steps that Appellant considers to be part of the invention, claim 1 does not include language requiring the flag to be present at the onset of the current cardiac cycle. In other words, in the method recited in

claim 1, this triggering event may not occur.[2] Therefore, the action triggered by this condition (the "precluding" step) is not necessarily required by the broadest reasonable interpretation of claim 1. Claim 1 covers two possible scenarios. In one scenario, the flag is present at the onset of the current cardiac cycle, and the precluding step is performed. In the other scenario, the flag is not present at the onset of the current cardiac cycle, in which case claim 1 requires no further action. In other words, claim 1 covers at least two methods, one in which the prerequisite condition (the flag being present at the onset of the current cardiac cycle) for the precluding step is met and one in which the prerequisite condition is not met. Nothing in claim 1 requires iterating the method until both events (the flag being present at the onset of the current cardiac cycle and the flag not being present at the onset of the current cardiac cycle) occur. Accordingly, under the broadest reasonable interpretation of claim 1, there is a scenario in which only the "setting" step is required be performed, and the given cycle is defined by an A-A interval. *See Ex parte Schulhauser*, Appeal No. 2013-007847 (PTAB April 28, 2016) (precedential) (stating that "[i]f the condition for performing a contingent step is not satisfied, the performance recited by the step need not be carried out in order for the claimed method to be performed" (quotation omitted)).

Claim 6

Addressing the rejection of claim 6, Appellant makes similar arguments to those made above for claim 1 (*see, e.g.*, Appeal Br. 10–11; *see also* Reply Br. 7), and for the reasons discussed above, we are not persuaded by these arguments.

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[2] Although the "setting" step in claim 1 causes a flag to be set, this step does not require the flag to be present at the onset of the current cardiac cycle.

Additionally, independent claim 6 recites, in part, "further comprising initiating an atrial escape interval at a start of the current cardiac cycle if the flag is present at the onset of the current cardiac cycle." Appeal Br. 14 (Claims App.).

The Examiner finds that Limousin discloses this feature inasmuch as, in the AAI mode, Limousin initiates an atrial escape interval to be shortened. Final Act. 5 (citing Limousin, 3:45–59).

Appellant asserts,

> claim 6 more specifically sets forth the flag being set at the onset of an atrial escape interval. Neither Reuter nor Limousin discloses this aspect of the operation of the devices therein in the DDD mode. In addition, this limitation further moots any possible argument by the Examiner that the cardiac cycles of the claims could possibly be read on AV and VA intervals during the same atrial escape interval (A-A interval) defined by the device. Finally, this limitation also moots any possible argument by the Examiner that the current cardiac cycle can be the cardiac cycle in which the V-event flag was set.

Appeal Br. 11.

Appellant's argument does not address the Examiner's finding that Limousin initiates an atrial escape interval in the AAI mode. Thus, this argument is unpersuasive, and we affirm the Examiner's rejection of claim 6. Claims 7–9 depend from claim 6 (Appeal Br. 14–15 (Claims App.)), and Appellant makes no additional arguments for the patentability of these claims (*see* Appeal Br. 12–13). Accordingly, we affirm the rejection of claims 7–9 as unpatentable over Limousin and Rueter.

Additionally, we note that the step of initiating an atrial escape interval is contingent upon the presence of the flag at the onset of the current cycle, and, as discussed above, the flag may not be present at the onset of this cycle. Accordingly, the "initiating" step in claim 6 is not necessarily

required under the broadest reasonable interpretation of the claim. As our claim interpretation for claim 6 is different from the Examiner's, as was our interpretation of claim 1, and we designate our affirmance of the rejection of claims 6–9 as a NEW GROUND of rejection.

Claim 10

Claim 10 recites the "setting" and "precluding" steps of claim 1, but, unlike claim 1, also specifies the actions taken if the flag is *absent* at the onset of the current cardiac cycle. Appeal Br. 15 (Claims App.). Claim 10 does not require iterating the method until all possible scenarios are exhausted. Accordingly, under the broadest reasonable interpretation of claim 10, it was necessary for the Examiner to address *either* (i) the actions taken when the flag is *present* at the onset of the current cardiac cycle, or (ii) the actions taken when the flag is *absent* at the onset of the current cardiac cycle, but not necessarily both. We addressed the actions in option (i) above with respect to claim 1, and for the same reasons, we affirm the Examiner's rejection of claim 10 as unpatentable over Limousin and Rueter. Claims 11 and 12 depend from claim 10 (Appeal Br. 15 (Claims App.)), and Appellant makes no additional arguments for the patentability of these claims (*see* Appeal Br. 12–13). Accordingly, we affirm the rejection of claims 11 and 12 as unpatentable over Limousin and Rueter. As our affirmance of the rejection of claims 10–12 relies on a different claim interpretation than the one used by the Examiner, we designate it as a NEW GROUND of rejection.

DECISION

The Examiner's rejection of claims 1, 3, and 5–12 as unpatentable over Limousin and Rueter is affirmed. We designate our affirmance of the rejection of claims 1, 3, and 5–12 as a new ground of rejection.

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). Section 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." Section 41.50(b) also provides:

> When the Board enters such a non-final decision, Appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:
>
> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new Evidence not previously of Record is made which, in the opinion of the examiner, overcomes the new ground of rejection designated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED; 37 C.F.R. § 41.50(b)